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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,101	08/01/2003	Marco Ciufolini	065691-0332	1920

22428 7590 09/27/2006

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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT PAPER NUMBER

1626

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/632,101	Applicant(s) CIUFOLINI ET AL.	
	Examiner Laura L. Stockton, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 14, 2006 & July 14, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 54-76 and 78--81 is/are pending in the application.
- 4a) Of the above claim(s) 55-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 54, 61-76 and 78-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1, 54-76 and 78-81 are pending in the application.

Continued Prosecution Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 14, 2006 has been entered.

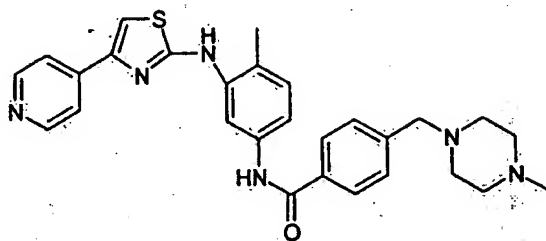
Election/Restrictions

Applicants' election without traverse of modified Group II, and the species of Example 80 found on pages

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64-65 of the instant specification (reproduced below), in the reply filed on July 15, 2005 was acknowledged in a previous Office Action. Modified Group II embraces wherein R⁶ represents the definition of (i), (ii) and (iii).

080: 4-(4-Methyl-piperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-4-yl-thiazol-2-ylamino)-phenyl]-benzamide



The requirement was deemed proper and made FINAL in a previous Office Action.

Subject matter not embraced by modified Group II and claims 55-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being

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drawn to nonelected inventions. Election was made **without** traverse in the reply filed on July 15, 2005.

Rejections made in the previous Office Action that do not appear below have been overcome. Therefore arguments pertaining to these rejections will not be addressed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 54, 61-76 and 78-81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s),

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at the time the application was filed, had possession of the claimed invention.

No persuasive support could be found in the specification or the originally filed claims for the expression "bearing at least one nitrogen group" found in claims 1, 62-67 and 69. Applicants allege support for this expression on page 11, lines 3-4 and on page 17, lines 5-10; and specifically, structures (a)-(f) on page 17. However, such showing for this expression is not found persuasive because this expression is not found in either location. Therefore, the claims lack written description as such.

Response to Arguments

Applicants' arguments filed June 14, 2006 have been fully considered. Applicants argue that: (1) support for the expression "bearing at least one nitrogen group" is found on page 11, lines 3-4 and on page 17, lines 5-10; and specifically, structures (a)-(f) on

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page 17; (2) the specification provides examples of specific compounds bearing a pendant basic nitrogen functionality; and (3) the written description requirement does not require *ipsis verbis* support.

All of Applicants' arguments have been considered but have not been found persuasive. The language "bearing at least one nitrogen group" was not found in either locations of the specification identified by Applicants. The specific examples on page 17 have been considered. If Applicants were to add these specific examples to the instant claims, the rejection would be overcome. The rejection is deemed proper and is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 61 and 63-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 61, there are specie listed which are not embraced by independent claim 1. See, for instance:

- d) compound xxv (Example 61 on page 52);
- e) compound lxix (Example 49 on pages 47-48);
- h) compound ci (Example 94 on page 26);
- i) compound cii (Example 95 on page 27);
- j) compound lxii (Example 26 on page 35); etc.

In claims 63-65, there is a valence problem with the R substituent "sulfonyl".

Response to Arguments

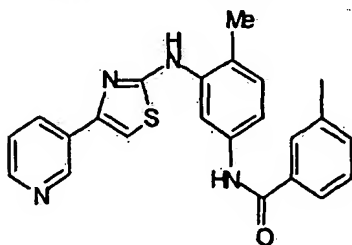
Applicants' arguments filed June 14, 2006 have been fully considered. Applicants argue that: (1) compounds

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xxv, lxix, ci, cii and lxii found in instant claim 61 are embraced by claim 1 when R^1 is defined as $-C(O)R$, $-C(O)OR$ or $-CONRR'$ wherein R and R' are independently selected from the group consisting of hydrogen, aryl, heteroaryl, alkyl and cycloalkyl, each optionally substituted with a heteroatom and/or bearing at least one nitrogen; and (2) claims 63-66 have been amended these claims rendering the rejection moot.

In response, compounds xxv, lxix, ci, cii and lxii found in instant claim 61 are not embraced by claim 1. Compound xxv, for example, is the same compound as Example 61 found on page 52 of the instant specification. See following reproduced structure.

061: 3-Methyl-N-[4-methyl-3-(4-pyridin-3-yl-thiazol-2-ylamino)-phenyl]-benzamide



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For Compound xxv, the R¹ variable represents -C(O)R, R represents an aryl group. However, claim 1 does not indicate that the aryl group can be substituted with a group such as alkyl (note that the phenyl ring of the benzamide group is substituted with a methyl group). An "alkyl" does not have a heteroatom nor does an "alkyl" bear at least one nitrogen group, which are the only two possible substituents on the aryl group defined by the instant R variable. Therefore, Compound xxv is not embraced by instant claim 1. Further, the "sulfonyl" substituent under the definition of the R variable in claims 63-65 is still present in these claims. The rejection is deemed proper and therefore, the rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise

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extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 54, 61-76 and 78-81 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No.

10/523,018. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed compounds are generically described in 10/523,018. Note claim 1 in each of the applications and especially note the compound claimed in claim 18 of 10/523,018, which is

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the same compound as the first compound listed in instant claim 43.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., c-kit inhibitors). The motivation to make the claimed compounds derives from the expectation that the instant claimed compounds would possess similar activity to that which is claimed in the reference.

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be c-kit inhibitors. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants' arguments filed June 14, 2006 have been fully considered. Applicants state that since the rejection is provisional, Applicants will address the rejection if it ever becomes a non-provisional rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

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said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 54, 61 and 73-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lago {WO 00/33842}, Dexter et al. {U.S. Pat. 3,467,666}, Spivack et al. {U.S. Pat. 3,201,409}, Illig et al. {U.S. Pat. 6,291,514}, Stieber et al. {U.S. Pat. 2003/0158199}, and Dhanoa et al. {U.S. Pat. 2001/0044545}, each taken alone or in combination with each other when similar activities are asserted.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim substituted phenylamino-2-thiazole compounds. Lago (pages 2-8; and especially the compound on page 3, line 17), Dexter et al. (columns 1-2; column 3, lines 35-38; and especially the compound of Example 13 in column 9), Spivack et al. (column 1; and especially the compound of Example 19 in column 9), Illig et al. (columns 4-5; Formula IV in column 17; columns 24-27; and especially the compound in column 18, lines 25-26), Stieber et al. (page 2; and

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especially Compound No. 17 on page 7; and Compound No. 35 on page 10) and Dhanoa et al. (page 3; Formula III on page 4; the compositions on pages 8-9; and especially compound 24 on page 6, paragraph [0120]) each teach substituted phenylamino-2-thiazole compounds that are structurally similar to the instant claimed compounds.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

The difference between the compounds of Lago, Illig et al., Stieber et al. and Dhanoa et al. and the instant claimed compounds is that the instant claimed compounds are generically described in the prior art.

The difference between the compounds of Dexter et al. and Spivack et al. and the compounds instantly claimed is that of a hydrogen versus a methyl on a phenyl ring (see the instant R⁴ variable definition).

***Finding of prima facie obviousness--rational and motivation (MPEP
§2142-2413)***

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., antagonizing the myt1 kinase receptor).

Further, it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and In re Lohr, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., a muscle relaxant).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of

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obtaining additional beneficial products which would, for example, antagonize the myt1 kinase receptor. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

Response to Arguments

Applicants' arguments filed June 14, 2006 have been fully considered. Applicants argue that: (1) there is no teaching or suggestion in the prior art to modify the cited prior art to arrive at the claimed invention; (2) MYTI kinase, which belongs to the Casein Kinase I family, has structure and properties vastly different from stem-cell factor receptors, such as c-kit; and (3) the claimed compounds and the compounds disclosed by the cited prior art references were tested and it was determined that the claimed compounds have superior and unexpected properties and were selective in inhibiting c-kit.

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All of Applicants' arguments have been considered but have not been found persuasive. Each of the cited prior art references do provide motivation to prepare the instant claimed compounds as discussed above in the rejection. Further, there is no requirement that the prior art must suggest that the claimed product will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. In re Dillon, 16 U.S.P.Q. 2d 1897, 1904 (Fed. Cir. 1990).

However, some of the cited prior art teach that their compounds have at least one or more of the same utilities that Applicants have disclosed in the instant specification. Lago (page 7, line 12) teaches treating rheumatoid arthritis and the instant specification discloses that rheumatoid arthritis can be treated by administering the instant claimed compounds (page 91, line 15). Illig et al. (column 3, lines 54-58) teaches treating psoriasis and the instant specification

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discloses that psoriasis can be treated by administering the instant claimed compounds (page 91, line 17). Stieber et al. (claim 14 on page 18, column 2) teaches inhibiting protein kinase activity wherein the kinase is c-kit and the instant specification discloses c-kit inhibitors (page 1, lines 10-11). Dhanoa et al. (page 2, paragraph [0026]) teaches treating diabetic complications and the instant specification discloses that diabetes mellitus and its chronic complications can be treated by administering the instant claimed compounds (page 91, line 6). A compound and its properties are inseparable. In re Papesch, 137 USPQ 43 (CCPA 1963).

Additionally, Applicants have not provided any factual proof in a side-by-side showing of unexpected results that the instant claimed compounds possess unexpected, superior and beneficial properties over the compounds of the prior art. Applicants have only alleged that testing was done and unexpected results

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were obtained but did not present the showing and data in a 35 USC 1.132 Declaration nor did Applicants identify which of the instant specie disclosed in the instant specification that were used in the testing. The instant claimed compounds would have been suggested and therefore, obvious to one skilled in the art. The rejection is deemed proper and therefore, the rejection is maintained.

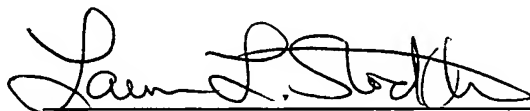
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact

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the Electronic Business Center (EBC) at 866-217-9197
(toll-free).

The Official fax phone number for the organization
where this application or proceeding is assigned is
(571) 273-8300.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

September 21, 2006